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BARD PERIPHERAL VASCULAR, INC.

UNITED STATES DISTRICT COURT

FOR THE CENTRAL DISTRICT OF CALIFORNIA

DAVID AND STACY WOOLLEY, individuals,

Plaintiffs,

v.

C. R. BARD, INC. and BARD PERIPHERAL VASCULAR, INC.,

Defendants.

Case No.: 8:16-cv-00698-MWF-PJW

Assigned to Hon. Michael W. Fitzgerald

DEFENDANTS' STATEMENT OF UNCONTROVERTED FACTS AND CONCLUSIONS OF LAW IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT OR, IN THE ALTERNATIVE, PARTIAL SUMMARY JUDGMENT

[Notice of Motion and Motion for Summary Judgment; Memorandum of Points and Authorities; Declaration of Jordan Grotzinger; and [Proposed] Order Filed Concurrently Herewith]

Date: January 24, 2022
Time: 10:00 a.m. PDT
Place: 350 West 1st Street, 9th Fl. Los Angeles, CA, 90012
Courtroom: Video Conference

Pursuant to Federal Rule of Civil Procedure 56 and Local Rule 56-1, Defendants C. R. BARD and BARD PERIPHERAL VASCULAR, INC. (collectively, "Bard") hereby submit this Statement of Uncontroverted Facts and Conclusions of Law in support of Defendants' Motion for Summary Judgment or, in the Alternative, Partial Summary Judgment.

I. STATEMENT OF UNCONTROVERTED FACTS

Uncontroverted Facts	Supporting Evidence[1]
1. Plaintiff David Woolley received a Bard G2® Filter on September 5, 2006 at UC Irvine Medical Center in Orange, California.	Ex. A, supplemental Plaintiff Fact Sheet of Plaintiff David Woolley, dated August 25, 2020 (hereinafter "PFS"), at 6-7
2. Bard's G2® Filter is a prescription inferior vena cava filter, illustrated in the below picture.  G2® Filter System	Ex. B, G2® Filter Instructions for Use (the "G2® IFU") at 11
3. The Filter is not sold directly to patients.	Ex. B, G2® IFU at 3
4. The Filter was cleared by the FDA for permanent use on August 29, 2005, and for retrievable use on January 15, 2008 through the 510(k) process outlined in the federal Food, Drug, and Cosmetic Act.	Ex. C, August 29, 2005 FDA Clearance Letter; Ex. D, January 15, 2008 FDA Clearance Letter; *see also* Traditional 510(k), G2 Filter with Femoral Delivery (Aug. 29, 2005), https://www.accessdata.fda.gov/cdrh_docs/pdf5/K050558.pdf.; Traditional 510(k), Recovery G2 Filter System – Femoral and Jugular/Subclavian Delivery Kits (Jan. 15, 2008), (https://www.accessdata.fda.gov/

[1] All Exhibits referenced herein were attached to the Declaration of Jordan Grotzinger in support of Bard's Motion for Summary Judgement, filed concurrently herewith.

Uncontroverted Facts	Supporting Evidence[1]
	cdrh_docs/pdf7/K073090.pdf)
5. Plaintiff David Woolley ("Mr. Woolley") suffered multiple traumatic injuries, including a crushed pelvis, following a car accident on September 3, 2006.	Ex. E, Selected Plaintiff Medical Records at WOOLLEYD_UCIMC_MDR00353-356, 363-369
6. Mr. Woolley was driving the car and was ultimately convicted of a DUI in connection with the accident.	Ex. F, September 15, 2020 Plaintiff David Woolley Deposition Transcript ("D. Woolley Depo.") at 89:13-25
7. Mr. Woolley's passengar in the car, who was his girlfriend at the time, died from her injuries.	Ex. F, D. Woolley Depo., at 90:1-7
8. During hospitalization Mr. Woolley was determined to be a very high risk for deep vein thrombosis and possible pulmonary embolism, due to his pelvic injuries and inability to anticoagulate.	Ex. G, Lane Dep. Tr. at 59:2-19
9. Plaintiff received the Bard G2® Filter without incident on September 5, 2006.	Ex. E, Selected Plaintiff Medical Records at WOOLLEYD_UCIMC_MDR00031-32, 337-338, 377, 386, 448, 456-461
10. Informed consent for the implant procedure was obtained by assisting physician Dr. Fairbanks, either from Plaintiff or Plaintiff's representative.	Ex. E, Selected Plaintiff Medical Records at WOOLLEYD_UCIMC_MDR00613-614
11. Dr. Fairbanks worked as a resident alongside Dr. Lane at UC Irvine Medical Center in Orange, California.	Ex. G, November 6, 2020 Dr. John Lane Deposition Transcript ("Lane Dep. Tr.") at 25:8-12, 32:10-33:10

Uncontroverted Facts	Supporting Evidence[1]
12. Plaintiff was told that his filter was placed to prevent pulmonary emboli.	Ex. F, D. Woolley Depo., at 88:24-89:4; 115:20-116:7
13. After implant, Plaintiff was transferred to Western Medical Detention Facility in connection with criminal charges related to the car accident.	Ex. E, Selected Plaintiff Medical Records at WOOLLEYD_UCIMC_MDR00357-358, 407-408, 413-414
14. Sometime in December 2014, Mr. Woolley presented to an urgent care facility with chest pain. He was diagnosed with gastroesophagael reflux disease ("GERD") and sent home.	Ex. F, D. Woolley Depo., at 117:17-118:12
15. On January 9, 2015, Plaintiff presented to the Emergency Room at Mills Peninsula Medical Center in Burlingame, California, with complaints of chest pain.	Ex. E, Selected Plaintiff Medical Records at WOOLLEYD_MPMC_MDR00013-18
16. It was determined Mr. Woolley's G2® Filter, which had remained since 2006, had migrated and fractured. One strut had emoblized to the heart, one was visible in the wall of his IVC, and one was within the pulmonary artery branch in the right lower lobe of the lung.	Ex. E, Selected Plaintiff Medical Records at WOOLLEYD_MPMC_MDR00024-28
17. On January 11, 2015, Mr. Woolley's IVC filter was removed without incident by Dr. Raju Gandhi.	Ex. E, Selected Plaintiff Medical Records at WOOLLEYD_MPMC_MDR00036-38
18. On January 11, 2015, Dr. Tomomi Oka performed a sternotomy to remove the strut in Mr. Woolley's heart.	Ex. E, Selected Plaintiff Medical Records at WOOLLEYD_MPMC_MDR00039-40

Uncontroverted Facts	Supporting Evidence[1]
19. Dr. Oka, along with other members of Plaintiff's care team, determined the strut in Plaintiff's IVC and the strut in Plaintiff's lung would remain, as they would be difficult to remove.	Ex. K, October 13, 2020 Deposition Transcript of Tomomi Oka, M.D. ("Oka Dep. Tr."), at 21:8-20
20. Mr. Woolley did not preserve his G2 filture after explant.	Ex. A, supplemental Plaintiff Fact Sheet of Plaintiff David Woolley, dated August 2, 2020 (hereinafter "PFS"), at 10
21. On March 2, 2015, Mr. Woolley reviewed his post-operative imaging with Dr. Wang Teng. They discussed the stability of the remaining two filter fragments – the fragment in the wall of the IVC, and the fragment in the right pulmonary artery. Dr Oka noted Mr. Woolley was doing well postoperatively.	Ex. E, Selected Plaintiff Medical Records at WOOLLEYD_SOCSMG_MDR00012
22. On April 27, 2015 Mr. Woolley had an office visit with treating physician Dr. Paul Drury, at which he elected not to have the two remaining filter struts removed. Dr. Oka noted Mr. Woolley had no shortness of breath and only occasional chest and shoulder pain.	Ex. E, Selected Plaintiff Medical Records at WOOLLEYD_PCAMG_MDR00003-5
23. When asked to describe the bodily injuries that Plaintiff attributes to the Filter, Plaintiff wrote in the Plaintiff Fact Sheet: "Knowing that I have two remaining struts that are like 'time bombs' waiting to result in devastating complications is very psychologically anxietizing."	Ex. A, PFS, at Ex. 12(a)

Uncontroverted Facts	Supporting Evidence[1]
24. Plaintiff attributes periodic chest pain around the surgical site to his filter removal surgery, as well as periodic shortness of breath, soreness around his scar when touched, mild pain after physical activity, and periodic heart palpitations	Ex. F, D. Woolley Depo., at 43:20-44:5, 52:8-11, 57:69-18, 57:19-58:8, 58:9-14
25. Plaintiff writes he is "embarassed and hesitant to remove his shirt" at the beach or public pools because of the scar on his chest from the filter removal surgery.	Ex. A, PFS, at Ex. 12(a)
26. On April 27, 2015, Mr. Woolley was seen by Dr. Paul Drury. The records note he has no shortness of breath and is "doing well with no residual symptoms" and "no cardiac limitations to activity."	Ex. E, Selected Plaintiff Medical Records at WOOLLEYD_PCAMG-MDR00003-5
27. Mr. Woolley testified he was instructed to go to the Emergency Room if he experiences chest pain, as it could mean an additional strut is migrating.	Ex. F, D. Woolley Depo., at 50:10-51:2
28. When asked whether he has gotten a medical opinion as to what's causing his chest pain, Mr. Woolley replied "I don't want to quote anything anyone has told me."	Ex. F, D. Woolley Depo., at 50:10-15
29. Mr. Woolley estimates he has been to the Emergency Room three to four times since his filter removal in 2015. He goes in anytime he is personally concerned about his chest pain	Ex. F, D. Woolley Depo., at 60:11-18, 61:3-10
30. Mr. Woolley testified his general diagnosis is "residual pain" with no particular cause, and he has been told it is not uncommen for someone who has had a sternotomy.	Ex. F, D. Woolley Depo., at 62:9-20

Uncontroverted Facts	Supporting Evidence[1]
31. Mr. Woolley considers himself to be in good health. He regularly rides his bike 6-8 miles and sometimes up to 20 miles. He regularly hikes, walks and uses a stand-up paddleboard. He is not currently taking any medications.	Ex. F, D. Woolley Depo., at 11:24-25, 13:24-14:2, 14:7-15:9, 15:11-25
32. When asked whether he experiences any cardiac limitations to activity currently, Mr. Woolley conceded he had no medical authority to establish that.	Ex. F, D. Woolley Depo., at 144:20-145:1
33. Mr. Woolley was on medical leave for 5-6 weeks after his steronomy, during which time he was paid a reduced salary.	Ex. F, D. Woolley Depo., at 83:4-17
34. Mr. Woolley testified he cannot state with any degree of certainty that but for his surgery he would be in a higher-paying position, and that such a statement would be speculative.	Ex. F, D. Woolley Depo., at 85:6-25
35. When asked whether a medical professional has told him there is a risk of future migration by his remaining filter struts, Mr. Woolley responded yes, but he "can't name names. I don't know who and when."	Ex. F, D. Woolley Depo., at 139:1-6
36. The G2 IFU applicable when Mr. Woolley received his Filter in 2006 contains specific warnings regarding the risks of filter tilt, migration, fracture, and perforation.	Ex. B, G2 IFU
37. Specifically, the IFU states: a. Under the bolded headings "**Warnings**" and "**Potential Complications**," the G2 IFU reads, in part, that "[p]ossible complications include, but are not	Ex. B, G2 IFU at 5 (emphasis in original)

Uncontroverted Facts	Supporting Evidence[1]
limited to, the following": • "Movement, migration or tilt of the filter are known complications of vena cava filters." • "Filter fractures are a known complication of vena cava filters." • "Acute or recurrent pulmonary embolism" • "Deep vein thrombosis" • "Restriction of blood flow" • "Occlusion of small vessels" • "Insertion site thrombosis" • "Vessel injury" • "Filter [t]ilt" • "Organ injury" • "**All of the above complications may be associated with serious adverse events such as medical intervention and/or death. There have been reports of complications including death, associated with the use of vena cava filters in morbidly obese patients. The risk/benefit ratio of any of these complications should be weighed against the inherent risk/benefit ratio for a patient who is at risk of pulmonary embolism without intervention.**"	
38. Plaintiff's implanting physician, Dr. John Lane, is dual board certified surgeon in both genera land vascular surgery with extensive experience	Ex. G, Lane Dep. Tr., at 25:8-12, 32:10-33:10

Uncontroverted Facts	Supporting Evidence[1]
placing IVC Filters like the one he implanted in Mr. Woolley.	
39. Dr. Lane received training in the use and implantation of inferior vena cava filters through his surgery fellowship, and during his time serving as the chief of vascular surgery at San Francisco General Hospital and his work as an associate professor of clinical surgery at UC Irvine.	Ex. G, Lane Dep. Tr. at 32:10-33:10
40. Dr. Lane testified that per the records, he treated Mr. Woolley by implanting the Filter on September 3, 2006, and does not recall treating Plaintiff subsequently.	Ex. G, Lane Dep. Tr. at 22:21-23:8
41. Dr. Lane testified that an IVC filter is a device that "provides filtration for blood," in order to prevent pulmonary emoblism	Ex. G, Lane Dep. Tr. at 33:18-34:9
42. Dr. Lane testified that a pulmonary embolism is a "potentially fatal" medical condition.	Ex. G, Lane Dep. Tr. at 34:10-13
43. Dr. Lane intended Mr. Woolley's Filter be temporary, and removed when it was no longer necessary to prevent DVT.	Ex. G, Lane Dep. Tr. at 61:8-62:11
44. Dr. Lane felt the G2 Filter was the best filter on the market at the time of Mr. Woolley's implant, "as far as its design, its filtration," and its indication for retrieval. He believed it "had the best combination of being an effective filter, being easy to place, being easy to	Ex. G, Lane Dep. Tr. at 22:7-20

Uncontroverted Facts	Supporting Evidence[1]
remove," and he did not have any poor outcomes with his patients	
45. Dr. Lane continues to implant Bard filters in his patients.	Ex. G, Lane Dep. Tr. at 33:1-15
46. Dr. Lane testified that he does a risk-benefit assessment for every individual patient and every procedure he performs.	Ex. G, Lane Dep. Tr. at 44:16-45:25
47. Dr. Lane was aware of the risks associated with IVC filters before September of 2006, including the risk of migration and fracture, and it is his standard practice to detail this with his individual patients prior to filter placement	Ex. G, Lane Dep. Tr. at 46:2-48:6
48. Dr. Lane testified that these risks are inherent to all filters, rather than associated only with Bard filters	Ex. G, Lane Dep. Tr. at 49:6-10
49. Dr. Lane educated himself on the risks associated with filters through the IFU as well as the medical literature, case reports, and professional communications, including his involvement in the academic community as an associate professor of surgery	Ex. G, Lane Dep. Tr. at 49:11-50:14
50. Dr. Lane also gained knowledge of Bard IVC filters through his work as a consultant for Bard.	Ex. G, Lane Dep. Tr. at 17:12-21

Uncontroverted Facts	Supporting Evidence[1]
51. Dr. Lane does not specifically recall reviewing the IFU for the G2 filter, but it was his general practice to do so when he was educating himself on a device	Ex. G, Lane Dep. Tr. at 52:18-53:7
52. Dr. Lane acknowledged the IFU for the G2 filter included warnings about the risks he was independently aware of, including fracture and migration	Ex. G, Lane Dep. Tr. at 54:12-55:23
53. Dr. Lane testified, per the records, that Mr. Woolley was "a typical case" of a patient who had suffered a crushed pelvis and lower extremity injuries. This put him at a high risk for DVT, because he was immobilized and unable to be anticoagulated with medication. Thus, the filter was prophylactically placed to prevent "the potentially fatal outcome of having a pulmonary embolus."	Ex. G, Lane Dep. Tr. at 59:2-19
54. Dr. Lane's best medical jugdment was that, notwithstanding the risks associated with filters, the benefit to Mr. Woolley outweighed them	Ex. G, Lane Dep. Tr. at 66:20-24
55. Dr. Lane's procedure notes state "The patients understands the risks of the procedure incluidng but not limited to… migration of the filter, and possible need for open operation," and were written within 24 hours of the procedure	Ex. G, Lane Dep. Tr. at 65:20-66:11
56. Dr. Lane implanted the G2 filter in Mr. Woolley's IVC without incident.	Ex. E, Selected Plaintiff Medical Records at WOOLLEYD_UCIMC_MDR00031-32, 337-338, 377, 386, 448, 456-461

Uncontroverted Facts	Supporting Evidence[1]
57. Dr. Lane was assisted in his care of Mr. Woolley by Dr. Timothy Fairbanks, a resident physician.	Ex. G, Lane Dep. Tr. at 65:4-19
58. It was the practice of both Dr. Lane and Dr. Fairbanks to discuss the risks of filter implant with the patient or the patient's representative in the event the patient was not conscious	Ex. G, Lane Dep. Tr. at 75:22-76:3
59. Dr. Lane did not conduct any follow-up care with Mr. Woolley, as he was transferred to Western Medical Detention Facility	Ex. G, Lane Dep. Tr. at 72:12-73:14, 82:11-83:13
60. Dr. Lane is not critical of his decision to implant the G2 Filter based on the information available to him at the time of implant in September 2006. He testified he made a "wise choice and there's nothing I would have done differently today based on that."	Ex. H, February 26, 2021 Deposition of Dr. Lane ("Lane Dep. Tr. II") at 204:8-22
61. Plaintiffs' counsel asked Dr. Lane about hypothetical risks with IVC filters but failed to connect these hypotheticals to whether it would have changed Dr. Lane's decision to prescribe the G2 filter.	Ex. G, Lane Dep. Tr. at 114:4-115:22
62. Dr. Scott Williams testified that he did not review or rely on any materials from Dr. Robert McMeeking in forming his opinion.	Ex. I, February 21, 2021 Dr. Scott Williams Deposition Transcript ("Williams Dep. Tr.") at 29:12-31:4
63. Dr. Williams opines Plaintiff developed DVT and interprets Plaintiff's 2015 imaging to show three embolized struts, in Plaintiff's heart, lung and IVC	Ex. L, Plaintiff's Rule 26(a) Disclosures, Ex. B, at 2-4

Uncontroverted Facts	Supporting Evidence[1]
64. Dr. Williams conceded he is not an engineer or an expert on IVC Filters or on medical device design.	Ex. I, Williams Dep. Tr., at 29:22-23, 67:22-68:16
65. Dr. Robert McMeeking testified that he has not met with David Woolley and has not reviewed all of his medical records.	Ex. J, March 16, 2021 Deposition Transcript of Dr. Robert McMeeking ("McMeeking Dep. Tr.") at 54:7-55:11
66. Dr. McMeeking has no opinion to a reasonable degree of medical certainty that Plaintiff suffered any physical injuries as a result of the alleged failure of his G2 filter.	Ex. J, McMeeking Dep. Tr., at 53:9-22
67. Dr. McMeeking testified that he has no opinion on Plaintiff's potenital for future complications related to his remaining filter struts, because he is not a medical doctor.	Ex. J, McMeeking Dep. Tr., at 49:25-50:17
68. Dr. McMeeking opines that the fracture and migration of Plaintiff's G2 Filter as identified by Dr. Williams are consistent with the failure modes he identifies in the G2.	Ex. L, Plaintiff's Rule 26(a) Disclosures, Ex. A, at 99

II. CONCLUSIONS OF LAW

1. In federal cases based on diversity jurisdiction, federal law determines procedural issues, and state law determines substantive issues. *See, e.g., Gasaway v. Nw. Mut. Life Ins. Co.*, 26 F.3d 957, 960 (9th Cir. 1994).

2. Thus, in this case, the Court will apply the federal summary judgment standard. *Snead v. Metro. Prop. & Cas. Ins. Co.*, 237 F.3d 1080, 1093 (9th Cir. 2001).

3. To obtain summary judgment, Bard must demonstrate an absence of disputed issue of material facts such that it is entitled to judgment as a matter of law. *See* Fed. R. Civ. P. 56(c).

4. Summary judgment is warranted if Plaintiffs cannot make a showing sufficient to establish each element for which they bear the burden of proof. *See Celotex Corp. v. Catrett*, 477 U.S. 317, 322-23 (1986).

5. Although the Court will view facts and inferences in the light most favorable to Plaintiffs, *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.,* 475 U.S. 574, 588 (1986), Plaintiffs must nonetheless offer some "concrete evidence from which a reasonable juror could return a verdict in [their] favor." *Anderson v. Liberty Lobby, Inc.,* 477 U.S. 242, 243, 256 (1986).

6. Concrete evidence requires more than a mere "scintilla" of evidence, *id*. at 252, and Plaintiff cannot avoid summary judgment simply by introducing conclusory allegations or speculation. *See, e.g., Cafasso, U.S. ex rel. v. Gen. Dynamics C4 Sys., Inc.*, 637 F.3d 1047, 1061 (9th Cir. 2011) ("To survive summary judgment, a plaintiff must set forth non-speculative evidence of specific facts, not sweeping conclusory allegations.").

7. Ultimately, "[s]ummary judgment has, as one of its most important goals, the elimination of waste of the time and resources and both litigants and the courts in cases where a trial would be a useless formality." *Zweig v. Hearst Corp.*, 521 F.2d 1129, 1135-36 (9th Cir. 1975), *disapproved of on other grounds by Hollinger v. Titan Capital Corp.*, 914 F.2d 1564 (9th Cir. 1990).

8. "The mere fact that the issues may be complex is not a valid reason to deny summary judgment when there is no genuine issue as to any material fact, and the movant is entitled to judgment as a matter of law. *Id.* at 1136.

9. Each and every one of Plaintiff's claims against Bard fails for lack of causation. Regardless of what theories Plaintiff pursues, it is axiomatic that Plaintiff must prove, through competent and reliable expert testimony, that Plaintiff's injuries were *caused* by some defect in his Filter. *See, e.g., Carson v. Depuy Spine, Inc.*, 365 F. App'x 812, 814 (9th Cir. 2010) (noting that "with any tort claim, the plaintiff must prove the alleged defect caused [the] injury").

10. In the medical device context, expert testimony is essential to prove a medical device caused the alleged injury, because "the complexity of the causation issue is beyond common experience." *Stephen v. Ford Motor Co*., 134 Cal. App. 4th 1363, 1373 (2005) ("A product liability case must be based on substantial evidence establishing both the defect and causation (a substantial probability that the design defect, and not something else, caused the plaintiff's injury) and where, as here, the complexity of the causation issue is beyond common experience, expert testimony is required to establish causation.").

11. A manufacturer is only liable on a products liability theory if a defect in the product caused the alleged injury. Restatement (Second) of Torts, § 430, cmt. A.

12. Medical causation must be proven to "a reasonable medical probability based upon competent expert testimony." *Jones v. Ortho Pharm. Corp.*, 163 Cal. App. 3d 396, 402-03 (1985). Courts in this district routinely grant summary judgment when a plaintiff lacks expert support for medical causation. *See, e.g., Sanderson v. Int'l Flavors & Fragrances, Inc.,* 950 F. Supp. 981, 1002-03 (C.D. Cal. 1996) (granting summary judgment for defendants because plaintiff presented no experts that could show medical causation and rejecting plaintiff's proposal to let a jury to use its "common sense" to infer causation from a temporal relationship between plaintiff's exposures and symptoms).

13. Even if this Court were to determine that Plaintiff's claims were not subject to dismissal due to Plaintiff's failure to prove causation, each of Plaintiff's causes of action fail for the additional reasons described below.

14. In this case, Plaintiff asserts failure to warn claims under both strict liability and negligence theories. To prevail, "[a] plaintiff asserting causes of action based on a failure to warn must prove not only that no warning was provided or the warning was inadequate, but also that the inadequacy or absence of the warning caused the plaintiff's injury." *Motus v. Pfizer Inc.* (*Motus I*), 196 F. Supp. 2d 984, 991 (C.D. Cal. 2001), *aff'd* 358 F.3d 659, 661 (9th Cir. 2004).

15. California applies the learned intermediary doctrine in cases involving medical devices. *See, e.g., Tucker v. Wright Med. Tech., Inc*., No. 11-cv-03086-YGR, 2013 WL

1149717, at *12 (N.D. Cal. Mar. 19, 2013) ("[T]he duty to warn the physician—rather than the patient—also applies to prescription implants.").

16. Under this doctrine, the manufacturer's duty to warn runs to the physician, not the patient. *Carlin v. Superior Court*, 13 Cal. 4th 1104, 1126 (1996); *Valentine v. Baxter Healthcare Corp.*, 68 Cal. App. 4th 1467, 1483 (1999).

17. Where the text of a warning is not in dispute, the adequacy of the warning may be determined as a matter of law. *Temple v. Velcro USA, Inc.*, 148 Cal. App. 3d 1090, 1094-95 (1983). An adequate warning is a complete defense to a product liability lawsuit. *Id.*

18. Where "the doctor testified that he did not read the warning label that accompanied [the prescription product] or rely on information provided by [defendant's] detail men before prescribing the [product] to [plaintiff], the adequacy of [defendant's] warnings is irrelevant to the disposition of this case." *Motus v. Pfizer Inc.* (*Motus II*), 358 F.3d 659, 661 (9th Cir. 2004); *Renteria v. Ethicon, Inc.*, 2020 WL 7414744, at *7 (C.D. Cal. Nov. 18, 2020) ("Where a physician did not read the manufacturer's product warnings, there is no causal connection on the failure to warn claim as a matter of law."); *Conte v. Wyeth, Inc.*, 85 Cal. Rptr.3d 299, 319 (Cal. App. 2008) ("There can be no proximate cause where, as in this case, the prescribing physician did not read or rely upon the allegedly inadequate warnings promulgated by a defendant about a product.").[2]

[2] *See also, e.g., Tucker v. Wright Med. Tech., Inc.*, 2013 WL 1149717, at *16 (N.D. Cal. Mar. 19, 2013) ("[w]here the physician did not read the warnings, adequacy is irrelevant"); *Phillippi v. Stryker Corp.*, 2010 WL 2650596, at *3 (E.D. Cal. Jul. 1, 2010) (where prescriber "received no direction or instruction from [defendant]," "[defendant] cannot be liable as a matter of law for an injury which . . . would be due solely to the doctor's decisions"), *aff'd*, 471 F. App'x 663 (9th Cir. 2012); *Hexum v. Eli Lilly & Co.*, No. 2:13-cv-02701-SVW-MAN, 2015 WL 4943959, at *6-7 (C.D. Cal. Aug. 18, 2015) (granting directed verdict where there was "no proof beyond speculation that [the prescriber] read [the drug's] label before prescribing it"); *Latiolais v. Merck & Co.*, No. CV 06–02208 MRP (JTLx), 2007 WL 5861354, at *3 (C.D. Cal. Feb. 6, 2007) ("where the prescribing doctor fails to read warnings or rely on information provided by the drug manufacturer before prescribing the drug, a plaintiff cannot show any alleged failure to warn by the drug manufacturer caused harm to the patient taking the drug"), *aff'd*, 302 F. App'x 756 (9th Cir.

19. "A plaintiff cannot prove that an allegedly inadequate warning was the proximate cause of his or her injury if the treating physician knew of the risk of harm plaintiff alleges to have suffered and prescribed the medication anyway." *Cleveland v. Janssen Pharm.*, No. 2:16-cv-02308 MCE AC PS, 2019 WL 6114719, at *10 (E.D. Cal. Nov. 15, 2019); *see also Plummer v. Lederle Labs.*, 819 F.2d 349, 359 (2d Cir. 1987) (applying California law, remarking that "no one needs notice of that which he already knows"); *Horton v. Endocare, Inc.*, No. B265724, 2016 Cal. App. Unpub. LEXIS 8154, at *17-18 (Cal. Ct. App. Oct. 28, 2016) (affirming summary judgment for lack of any evidence of causation where "[the physician] was independently aware of the risks associated with the [implantable medical device] and there was no evidence he would have treated [plaintiffs] differently had he received additional warnings from defendants"); *see also Webb v. Special Elec. Co.,* 63 Cal.4th 167, 182 (Cal. 2016) (sophisticated product users need not be warned about dangers of which they are already aware or should be aware); *accord Hammarlund v. C.R. Bard, Inc.*, No. 2:15-cv-05506-SVW-JEM, 2015 WL 5826780, at *7 (C.D. Cal. Oct. 2, 2015) ("Moreover, if a medical community has universally accepted the risks of a product, a failure to warn may not establish causation.")

20. A claim alleging a negligent failure to warn of the dangers of a prescription medical device requires a plaintiff to prove that a manufacturer did not warn of a particular risk for reasons that fell below the acceptable standard of care, based on what a reasonably prudent manufacturer would have known and warned about. *Bigler-Engler v. Breg, Inc.*, 7 Cal. App. 5th 276, 317 (2017); *Chavez v. Glock, Inc.*, 207 Cal. App. 4th 1283, 1305 (2012); *Carlin v. Superior Court*, 13 Cal.4th 1104, 1112 (Cal. 1996).

21. Under California negligence principles, a reasonably prudent manufacturer might reasonably decide that the risk of harm did not require a warning without liability.

2008); *Grove v. Boston Sci. Corp.*, No. 2:13-cv-15669, 2016 WL 2889070, at *3 (S.D.W. Va. May 17, 2016) (applying California law, remarking that "if a doctor did not read the warning . . . then the chain of causation is broken and a plaintiff cannot establish proximate causation").

Salinas v. Amteck of Kentucky, Inc., 682 F. Supp. 2d 1022, 4 (N.D. Cal. 2010); *Carlin v. Superior Court*, 13 Cal.4th 1104, 1112-1113 (Cal. 1996).

22. There is no duty to warn of the possibility of rare, remote, idiosyncratic, hypersensitive, or unusual reactions to an otherwise safe and useful product. *Friedman v. Merck Co., Inc.*, 107 Cal. App. 4th 454, 466 (2003).

23. Expert testimony is necessary to demonstrate negligent warnings in products liability cases involving medical devices. *Tucker v. Wright Med. Tech., Inc.*, No. 11-cv-03086-YGR, 2013 WL 1149717, at *15 (N.D. Cal. Mar. 19, 2013).

24. Under California law, "[i]n the context of medical devices, design defects must be pursued under a negligence theory." *Armstrong v. Optical Radiation Corp.*, 50 Cal. App. 4th 580, 595 (1996).

25. To determine whether a product is defectively designed, California applies "the 'risk-benefit' standard e. g., the feasibility and cost of alternative designs." *Barker v. Lull Engineering Co*., 573 P.2d 443, 455 (Cal. 1978); *Merrill v. Navegar, Inc*., 26 Cal.4th 465, 479-480 (2001) (applying risk-benefit test).

26. In a product liability action based on negligent design of a product placed on the market, courts must balance the likelihood of harm to be expected from a product as designed and the gravity of harm that would happen, against the burden of taking the precaution that would avoid the harm. *Roy v. Volkswagen of Am., Inc.*, 896 F.2d 1174, 1176 (9th Cir. 1990).

27. Expert testimony is necessary to demonstrate negligent design defect in products liability cases involving medical devices. *Tucker,* 2013 WL 1149717, at *15 (N.D. Cal. Mar. 19, 2013).

28. Plaintiff carries the burden of proof to establish a feasible alternative product design in negligent design cases. *See, e.g., Whiteley v. Philip Morris Inc*., 11 Cal. Rptr. 3d 807, 862-63 (Cal. App. 2004) (granting judgment n.o.v. on negligent design claims where plaintiffs could not prove that the alleged "negligence" – failure to adopt a safer alternative product design – caused the plaintiff's injuries); *McGinty v. Superior Court*, 31 Cal. Rptr.

2d 292, 294 (Cal. App. 1994) (in a "negligence cause[] of action . . . [o]ne element of [plaintiffs'] product liability action is to show the existence of an alternative feasible design for the product which would have been safer").

29. As with a general negligence claim, a plaintiff must show duty, breach, causation, and damages. *Mariscal v. Graco, Inc.*, 52 F. Supp. 3d 973, 990-91 (N.D. Cal. 2014).

30. Under California law, "if the same harm would have occurred without" defendant's conduct, there can be no liability. *See* CACI 430. In *Soule v. G.M. Corp.,* 8 Cal. 4th 548, 571 (1994), the defendants argued that plaintiff's injuries would have occurred without its conduct because the natural chain of events "would have caused identical injuries notwithstanding" an alleged product defect. *Id.,* at 572. In the case of medical treatment, the natural course of events for patients like Plaintiff would have required use of a product that carried the same or similar risks. *See, e.g.*, *In re NuvaRing Litig.*, 2013 WL 1874321, at *22 (N.J. Super. Ct. Law Div. Apr. 18, 2013) ("Plaintiff has not been able to provide evidence that the injury would have been prevented if Plaintiff had used another birth control method.").

31. There is no claim recognized in California for negligent sale of a prescription product that is regulated and cleared for sale by the FDA. Decisions to clear a medical device for sale or to remove it from the market are clearly within the jurisdiction of the FDA pursuant to the FDCA. *Mutual Pharmaceutical Co. v. Bartlett,* 570 U.S. 472 (2013). Any purported state law claims challenging the decisions of the FDA are preempted under the U.S. Supreme Court decision in *Buckman v. Plaintiffs' Legal Comm.,* 531 U.S. 341 (2001).

32. Reliance is an essential element of any claim for negligent or fraudulent misrepresentation, or fraudulent concealment. *See, e.g., Pooshs v. Philip Morris USA, Inc.*, 904 F. Supp. 2d 1009, 1026-27 (N.D. Cal. 2012) (misrepresentation and concealment require proof of reliance); *Marroquin v. Pfizer, Inc.*, 367 F. Supp. 3d 1152, 1165-66 (E.D. Cal. 2019) (same re intentional and negligent misrepresentation).

33. If the Court grants Bard's motion, and dismisses all of Plaintiff's underlying causes of action, Plaintiff Stacy Woolley's claim for loss of consortium must be dismissed as well. Two critical elements of a cause of action for loss of consortium require that a Plaintiff demonstrate 1) their spouse suffered a tortious injury, and 2) the plaintiff's loss of consortium was proximately caused by the defendant's act. *Vanhooser v. Sup. Ct.,* 206 Cal.App.4th 921, 927 (2012). Because a loss of consortium claim is necessarily dependent on the success of the underlying tort claim, if Plaintiff's tort claims fail, this claim must fail as well. *Blain v. Doctor's Co.,* 222 Cal.App.3d 1048, 1067 (1990)(holding that because Plaintiff had no cause of action in tort, his house had no cause action for loss of consortium).

34. If the Court grants Bard's motion, and dismisses all of Plaintiff's underlying causes of action, Plaintiff's claim for punitive damages must be dismissed as well. *See, e.g., Zakaria v. Gerber Prods. Co.*, No. LA CV15-00200 JAK (Ex), 2017 WL 9512587, at *23 (C.D. Cal. Aug. 9, 2017) (granting summary judgment on punitive damages claim where plaintiff lacked an underlying tort theory supporting the imposition of punitive damages), *aff'd* 755 F. App'x 623 (9th Cir. 2018) (unpublished); *Contento v. Mitchell*, 28 Cal. App. 3d 356, 357 (1972) ("It is a well-settled rule that there can be no award of punitive damages without a finding of actual damages."); *Marroquin*, 367 F. Supp. 3d at 1168 (punitive damages "merely an additional remedy that [are] dependent on a viable cause of action for an underlying tort").

35. Under California law, a plaintiff has the burden of establishing that he or she suffered compensatory damages as a proximate result of the conduct of the defendant before he or she is eligible to recover punitive damages. *Hilliard v. A.H. Robins Co.*, 148 Cal.App.3d 374, 396 (Cal. Ct. App. 1983).

36. "Under California law, punitive damages are allowed 'where it is proven by clear and convincing evidence that the defendant has been guilty of oppression, fraud, or malice.'" *Johnson Indus. Sales v. Strema Sales*, 224 F. App'x 709, 711 (9th Cir. 2007) (quoting Cal. Civ. Code § 3294(a)); *see also Rosa v. Taser Int'l, Inc.*, 684 F.3d 941, 949 n.7 (9th Cir. 2012) (to recover punitive damages, plaintiff "must demonstrate that defendant

acted with knowledge of the probable dangerous consequences to plaintiff's interests and deliberately failed to avoid these consequences" (citation and internal quotation marks omitted)).

37. "Malice" is defined as "conduct which is intended by the defendant to cause injury to the plaintiff or despicable conduct which is carried on by the defendant with a willful and conscious disregard of the rights or safety of others." Cal. Civ. Code § 3294(c)(1).

38. Evidence that a defendant's conduct was "negligent, grossly negligent or even reckless" is insufficient to support a claim for punitive damages. *See Gawara v. U.S. Brass Corp.*, 63 Cal. App. 4th 1341, 1360-62 (1998) (citation omitted).

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